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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ODLAND, KATHRYN P	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 08/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/897,295	BOYLE ET AL.	
	Examiner	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *14-19 and 27-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/01, 3/1,8/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species I in the reply filed on June 14, 2004 is acknowledged. Claims 1-13 and 20-26 are under consideration and claims 14-19 and 27-40 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Hopkins et al. in US Patent No. 6,544,279.

Regarding claim 1, Hopkins et al. disclose a restraining device for maintaining a self-expanding medical device on a delivery catheter having a restraining sheath (584) having an expandable housing portion (594) adapted to receive and maintain the self-expanding medical device (588 and associated components) in a collapsed condition on the delivery catheter, as recited in column 23 and seen in figures 23A-23B.

Regarding claim 2, Hopkins et al. disclose that as applied to claim 1, as well as an expandable housing portion (594) that is adapted to expand between a contracted position and an expanded position, the housing portion having sufficient column strength to maintain

the self-expanding medical device in its collapsed condition on its delivery catheter, as recited in column 23 and seen in figures 23A-23B.

Regarding claim 20, Hopkins et al. disclose that as applied to claim 2, as well as an expandable housing portion (594) that includes a low expansion section with at least one expansion member (such as 590) disposed within the low expansion section to provide the elasticity needed to move the housing portion between the contracted position and expanded position. "Low expansion section" is considered a relative phrase and a basis for comparison has not been provided.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 3-13 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hopkins et al. in US Patent No. 6,544,279 in view of Cryer et al. in US Patent No. 6,290,710.

Regarding claim 3, Hopkins et al. disclose that as applied to claim 2, as well as an expandable housing portion (594) that is made primarily from an elastic material, which is stretchable between the contracted position and expanded position. However, Hopkins et al. do not explicitly recite at least one reinforcing member associated therewith for providing additional column strength to the housing portion. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Cryer et al. teach reinforcement in column 8, lines 35-45. Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability.

Regarding claim 4, Hopkins et al. as modified disclose that as applied to claim 2, as well as a plurality of reinforcing members associated with the expandable housing portion to provide additional column strength to the housing portion is within the scope of this modification and would be obvious to one with ordinary skill in the art.

Regarding claim 5, Hopkins et al. as modified disclose that as applied to claim 4, as well as reinforcing members that extend substantially along the length of the expandable housing portion but do not interfere with the expansion of the elastic material is within the scope of this modification and would be obvious to one with ordinary skill in the art.

Regarding claim 6, Hopkins et al. as modified disclose that as applied to claim 5 as well as reinforcing members (braids) that are elongated bar-like members made from a material having high stiffness, as recited in column 8, lines 35-45.

Regarding claims 7 and 23, Hopkins et al. as modified disclose that as applied to claims 3 and 21 as well as Cryer et al. further teach an elastic material that is selected from a group of materials which includes silicone, polyurethane, polyisoprene, and lower durometer PEBAX, as recited in column 8, lines 35-45.

Regarding claim 8, Hopkins et al. as modified disclose that as applied to claim 4 as well as Cryer et al. further teach a reinforcing member that is made from a material selected from a group including stainless steel, polymeric material, and nitinol, as recited in column 8, lines 35-45.

Regarding claims 9 and 22, Hopkins et al. as modified disclose that as applied to claims 8 and 21 as well as radiopacity material (598). It would be further within the scope of the modification to have the reinforcing members loaded with a material having high radiopacity.

Regarding claim 10, Hopkins et al. as disclose that as applied to claim 1 as well as an expandable housing portion that is made from a substantially tubular-shaped material that is highly elastic. However, Hopkins et al. do not explicitly recite a plurality of reinforcing members disposed within the tubular elastic material to provide additional column strength

to the housing portion. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Cryer et al. teach reinforcement in column 8, lines 35-45. Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability.

Regarding claims 11-13, Hopkins et al. as disclose that as applied to claim 4. However the following claims disclose location options for the reinforcing members. Since no particular location has been deemed critical they can be considered equivalents. Thus, it would be within the scope of the modification to have the reinforcing members disposed within the elastic material forming the expandable housing portion, attached to the surface of the expandable housing portion, and/or disposed along the expandable housing portion.

Regarding claim 21, Hopkins et al. as disclose that as applied to claim 2. However, Hopkins et al. do not explicitly recite a plurality of low expansion sections and a plurality of expansion members disposed between low expansion sections. On the other hand, it would be obvious to one with ordinary skill in the art to incorporate reinforcing members. For example, Cryer et al. teach reinforcement in column 8, lines 35-45. Thus, it would be within the scope of the invention and obvious to one with ordinary skill in the art to incorporate reinforcement members in the expandable housing of Hopkins et al. for the purpose of controlling the expansion/rigidity. It is known to combine different materials to achieve different strengths and expansion ability. Further, to have the expansion members

disposed between the low expansion sections would further be obvious to one with ordinary skill in the art.

Regarding claim 24, Hopkins et al. as modified disclose that as applied to claim 23 as well as Cryer et al. teach low expansion sections that are made from a material selected from a group including cross-linked HDPE, polyolefin and polyamide, as recited in column 8, lines 35-45.

Regarding claim 25, Hopkins et al. as modified disclose that as applied to claim 21. Further, this modification would yield expansion members that extend longitudinally along the length of the expandable housing portion.

Regarding claim 26, Hopkins et al. as modified disclose that as applied to claim 25. Further, this modification would yield expansion members that include means for preventing the low expansion sections from tearing as the expandable housing portion expands from the contracted position to the expanded position.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US 2004/0044359; US 2002/0095170; US 2002/0058963; US 2002/0183781; US 2002/0107541; US Patent No. 6,685,722; US Patent No. 6,679,902; US Patent No. 6,383,206; US Patent No. 6,221,006; US Patent No. 6,171,327; and US Patent No. 5,766,203.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

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